UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES EX REL, ELLEN LEONARDI	:	**Civil Action No. 1:23-cv-00253**
	:	
	:	**Judge Black**
Plaintiff-Relator	:	
	:	**RELATOR'S FIRST AMENDED**
-vs-	:	**COMPLAINT WITH JURY DEMAND**
	:	
LIFE LINE COMMUNITY HEALTHCARE LLC	:	
	:	
	:	
Defendant	:	

I. INTRODUCTION

1. This is a *qui tam* action brought by Relator Ellen Leonardi ("Relator"), for herself and on behalf of the United States, to recover damages and civil penalties arising from Defendant Life Line Community Healthcare LLC aka Life Line Screening ("Life Line") for the submission of unlawful bills to the United States for reimbursement by its Medicare program in violation of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq.*

2. From at least April of 2020 through October of 2021, Life Line participated in a widespread, exclusive, and illegal nationwide scheme by presenting false medical claims to the United States. These medical claims include Medicare Part B requests for payment for services referred to as Annual Wellness Visits ("AWV"), Health Risk Assessments ("HRA") and Advance Care Planning ("ACP").

3. Life Line has knowingly presented or caused to be presented thousands, perhaps hundreds of thousands, of false claims to Medicare for payment or approval of services performed

by Life Line employees or third party contractors for Medicare insured patients who were not licensed to perform such services in the states or did not have a collaborative agreement for which a request for payment was made. These false claims were paid by the United States which resulted in millions of dollars of losses from the United States fisc.

4. As part of this widespread fraudulent scheme, Life Line falsely certified in its payment requests that there was no violation of the Medicare laws, regulations or the FCA.

5. Pursuant to the FCA, the Relator, on behalf of the United States, seeks recovery of damages and civil penalties for Life Line's presentment of false and improper charges representing claims for payment to Medicare.

II. JURISDICTION AND VENUE

6. This action arises under the FCA. Relator's state law claim in Count Three under Ohio law is based upon this Court's pendent jurisdiction under 28 U.S.C. §1367. The Court also has jurisdiction under Count Three based upon 28 U.S.C. §1332(a)(1) because the matter in controversy exceeds the sum or value of $75,000 exclusive of interest and costs and is between citizens of different states. Relator is a citizen of the State of Ohio and Defendant Life Line is a citizen of either the State of Texas as that is where it conducts its principal place of business, or Delaware, the state of its formation.

7. Jurisdiction over this action based upon Relator's federal claims is vested in this Court under 31 U.S.C. §3732(a) and 28 U.S.C. §1331.

8. Venue is proper in this district under 31 U.S.C. §3732(a). It is proper because Life Line transacts business within this district, and, as part of that business, it has presented numerous false claims for payment to the United States in connection with those claims.

9. Under 31 U.S.C. §3730 the original complaint was filed in-camera under seal. On December 13, 2023 the Court ordered the complaint to be unsealed. (Doc. 9). None of the allegations in this Complaint are based upon any public disclosure as defined under the FCA.

III. THE PARTIES AND RELATED ENTITIES

10. The real party in interest for the claims in this action is the United States.

11. Relator is a resident of the State of Ohio and a family Nurse Practitioner ("NP") who completed a graduate degree in advanced practice nursing and a certificate in family care. She is licensed in Illinois and most recently became licensed in Ohio. She was employed by Life Line her termination on December 17, 2021. Relator has first-hand knowledge of the facts alleged herein.[1]

12. Life Line claims to be a leader in the healthcare industry with a commitment to the provision of quality healthcare services to the senior population. It is an affiliate of Life Line Screening of America Ltd. It is a leading provider of Annual Wellness Visits ("AWV"), Health Risk Assessments ("HRA"), and Advance Care Planning ("ACP"). It offers a broad scope of health wellness and prevention services on a national basis. It directly or through an affiliate identified as Life Line Screening is the largest direct to consumer telehealth screening company in the United States.

13. AWVs are a comprehensive one-on-one consultation with a nurse practitioner for seniors – that is people 65 and over - to discuss their health and develop a prevention and wellness plan designed to help them remain healthy.

[1] Life Line filed a notice with the Ohio Unemployment Commission that the Relator had been terminated on or about December 17, 2021. (Attached as Exhibit 1). As described herein, Relator was not informed of her termination until February 2022.

14. The AWV is a service that Medicare B covers the complete cost and of which there is no out of pocket expense to the beneficiary. The AWV is preventive care which is designed to prevent disease and help a senior stay active longer. During the AWV, a licensed NP such as Relator provides services only to patients 65 years and older and engages in a detailed health discussion with that patient. See 42 C.F.R §410.15. The discussion includes:

- A review of the person's medical and family history.
- Screening for depression or cognitive impairments.
- A review of functional abilities, fall prevention, and home safety.
- Measurement of blood pressure and other biometrics deemed appropriate by your medical/family history.
- Personalized advice for health, nutrition and exercise, and/or referrals to health, education or other services as needed.
- A written screening and immunization checklist/schedule which is to last for the next 5 to 10 years as appropriate.[2]

15. Once the interviews are completed and written plans are prepared, Life Line bills every single AWV to Medicare Part B for reimbursement of the services performed by the nurse practitioner. For a first time visit, the services are billed under HCPCS Code G0438 for Medicare reimbursement of approximately $177.00. Every subsequent AWV service is billed on a yearly basis under HCPCS Code G0439 for approximately $128.00. These AWVs performed by Life Line NPs were the type of services Relator provided to Medicare Part B beneficiaries.

16. Although Relator was licensed in Illinois and provided services in Illinois, she was ordered by management at Life Line to unlawfully engage in providing NP services for

[2] Section 60.2 of the Medicare Claims Processing Chapter identifies how to bill AWVs to Medicare under HCPCS Codes G0438 and G0439.

beneficiaries seeking AWVs in states in which she was not licensed, she did not have a collaborative agreement, and did not meet the requirements of the state to provide care to its residents. Relator continued to ask Life Line management and its legal counsel for authority which would allow her to provide services in states for which she was not licensed and did not have a collaborative agreement. Life Line refused to provide that authority. Eventually, Relator was terminated from her employment for her efforts to stop one or more violations of Chapter 3729 and raising these issues to Life Line which were a violation of the FCA.

IV. THE LAW

A. The False Claims Act (31 U.S.C. §§ 3729-33).

17. The FCA provides for an award of treble damages and civil penalties against any person for, inter alia, knowingly causing the submission of false or fraudulent claims for payment to the United States Government or making or using false statements which are material to false or fraudulent claims paid by the United States.

18. The FCA, 31 U.S.C. §3729, imposes liability to persons for the following unlawful conduct:

> "(a) (1)(A) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made a false record or statement material to a false or fraudulent claim;
>
> (C) conspiring to commit a violation of subparagraphs (A), (B)…or (G);
>
> (G) knowingly makes or uses or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly or improperly avoids or decreases an obligation to pay or transmit money or property to the government."

Originally, a person who violated the FCA was liable to the United States government for a civil penalty of not less than $5,000 and not more than $10,000 for each claim. However, the FCA includes an inflationary adjustment provision pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public law 104-410) and as of 2024, Life Line is subject to penalties of between $13,946 to $27,894. Additionally, Life Line is subject to a maximum of three times the amount of damages the government sustained because of its unlawful acts.

19. Pursuant to 31 U.S.C. § 3729(b)(1)(A), the terms "knowing" and "knowingly" mean that a person, with respect to information - (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.

20. The FCA under 31 U.S.C. §3729(b)(1)(B) does not require specific proof of intent to defraud. Further, it defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money in payments." 31 U.S.C. §3729(h)(4).

21. The standard of proof under the FCA is a preponderance of the evidence. 31 U.S.C. §3731(c).

B. Federal Health Care Programs

22. In 1965 Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain health care services. The United States Department of Health and Human Services ("HHS") is responsible for administering and supervising the Medicare Program through the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS. Entitlement to Medicare is based on age, disability, or affliction

with end-stage renal disease. 42 U.S.C. §§426, 426A.

23. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries".

24. There are four parts to the Medicare Program: Part A authorizes payment for institutional care, including inpatient hospital care, skilled nursing facility care, and home health care (*see* 42 U.S.C. §§1395c-1395i-4); Part B primarily covers outpatient care, including physician services and ancillary services (42 U.S.C. § 1395(k); Part C is the Medicare Advantage Program, which provides Medicare benefits to certain Medicare beneficiaries through private health insurers (42 U.S.C. §1395w-21 *et seq.*); and Part D provides prescription drug coverage. (42 U.S.C. §1395w-101 *et seq.*; 42 C.F.R. §423.1 *et seq.).*

25. Since November 2006, CMS has contracted with Medicare Administrative Contractors (MACs) to assist in the administration of Medicare Parts A and B. *See* Fed. Reg. 67960, 68181 (Nov. 2006). MACs generally act as CMS's agents in reviewing and paying Part A and Part B claims submitted by healthcare providers and perform administrative functions on a regional level. 42 C.F.R. §421.5(b); 42 U.S.C. §§1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104.

26. When a physician or a healthcare provider provides patient care services, it must bill Medicare using a CMS Form 1500 for their "professional" services, which includes performing procedures and interpreting test results. The Form 1500 provides:

> Signature Of Physician Or Supplier (Medicare, Tricare, FECA And Black Lung)
>
> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the

> government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license#, or SSN) of the primary individual rendering each service is reported in the designated section. For services to be considered "incident to" a physician's professional services, 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.
>
> For TRICARE claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contract employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black-Lung claims, I further certify that the services performed were for a Black Lung-related disorder.
>
> No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 424.32). (Emphasis added)

27. Providers must be enrolled in Medicare in order to be reimbursed by the Medicare program. 42 C.F.R. §424.505.

28. Medicare enrollment regulations further require providers to certify that they meet, and will continue to meet, the requirements of the Medicare statutes and regulations. See 42 C.F.R. §424.516(a)(1). The regulations also require certification that the provider such as Life Line will maintain compliance with the Social Security Act, applicable Medicare regulations, and with Federal and state license certifications and regulatory requirements as required based upon the type

of services or supplies the provider or supplier will furnish and bill Medicare. See 42 C.F.R. §424.516(a)(1) and (2).

29. Payment of Medicare Part B physician and other healthcare claims are paid pursuant to a Medicare Program reimbursement schedule. Clinics, group practices, and other suppliers, as well as eligible, non-physician practices that meet Medicare requirements, enter into provider agreements such as CMS-855(B) and CMS-855(I). Upon information and belief, Life Line executed CMS Form 855B and/or 855(I) which contains the following language: "I agree to abide by the Medicare laws, regulations, [and] program instructions that apply. . . to me or the organization listed in Section 2(A)(1) of the application… ***I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions***…" The Medicare Enrollment Applications also summarize the FCA in a separate section that explains the penalties for falsifying information in the application to "gain or maintain enrollment in the Medicare program."

C. Implied Certification

30. Life Line certifies that it has complied with Medicare laws and regulations when presenting for payment those false claims derived from a Federal health care program that are the subject of this complaint.

31. Certification of compliance with Medicare laws and regulations is a prerequisite for home healthcare providers to obtain a government benefit such as Medicare and other payments from federal health care programs.

32. A false certification of compliance creates a liability under the FCA.

33. Under the implied certification theory, each time an illegal claim is submitted, that

claim is a separate claim that is actionable under the FCA. See, *United States ex rel Augustine v. Century Health Services*, 289 F.3d 409, 416 (6th Cir. 2002).

34. The violation of the Social Security Act, Medicare laws and regulations, and state laws may serve as a basis for a FCA lawsuit.

35. Each submission of a false claim by Life Line to the United States for payment for services related to a federally funded health program is, as a matter of law, a separate violation of the FCA.

D. State Licensing Requirements and Collaborative Agreements to Bill Medicare.

36. Federal law identifies the prerequisites for NPs to provide services which in turn permits the NPs or their employers to bill the United States government for those services.

37. 42 C.F.R. §410.1 sets forth the statutory basis for payments from the United States to NPs or other employes under Section 410. Subsection 410.1(a)(2)(b) states in relevant part:

> **(b)** ***Scope of part.*** This part [Section 410] sets forth the benefits available under Medicare Part B, the conditions of payment and the limitation on services, the percentage of incurred expenses that Medicare Part B pays, and the deductible and copayment amounts for which the beneficiary is responsible.

38. Within 42 C.F.R. §410, is a reference to what is described as a Preventive Service. A Preventive Service is defined in 42 C.F.R. §410.2 as an AWV providing Personalized Prevention Plan Services ("PPPS") as specified by Section 1861(hhh)(1) of the Act.

39. Section 410.15 permits reimbursement for AWVs. That section limits coverage and the payment to those NPs who meet the specific requirement for each state in which services were provided. Section 410.15 states in relevant part as follows:

> **§410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.**
>
> **a. Definitions**. For purposes of this section –
>
> Health professional means:
>
> (i) A physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); or
>
> (ii) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act);

40. Section 1861(aa)(5)(A) of the Social Security Act, 42 U.S.C. §139.54 ("The Act"), states:

> The term "physician assistant" and the term "nurse practitioner" mean, for purposes of this title, a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations. (Emphasis Added).

41. Further, under §410, in order for Life Line to legally bill Medicare for AWV services provided by an NP such as Relator, the NP must have met the statutory requirements set forth in 42 C.F.R. §410.75 et seq. That regulation states in relevant part:

> **(a)** ***Definition***. As used in this section, the term "physician" means a doctor of medicine or osteopathy, as set forth in section 1861(R)(1) of the Act.[3]
>
> **(b)** ***Qualifications***. For Medicare Part B coverage of his or her services, a nurse practitioner must be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with

[3]Pursuant to §1861(r)(1) of The Act (42 U.S.C. §1395x)", the term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. (Emphasis Added). This is the definition referred to in §410.75(a)

State law, and must meet one of the following:

. . .

(c) ***Services***. Medicare Part B covers nurse practitioners' services in all settings in both rural and urban areas, only if the services would be covered if furnished by a physician and the nurse practitioner –

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage because of one of the statutory exclusions; and

(3) Performs them while working on collaboration with a physician.

(i) Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed. (Emphasis Added).

(ii) In the absence of state law governing collaboration, collaboration is a process in which a nurse practitioner has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by nurse practitioners documenting the nurse practitioners' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Nurse practitioners must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the nurse practitioner when the services are furnished or to make an independent evaluation of each patient who is seen by the nurse practitioner.

(d) ***Services and supplies incident to a nurse practitioners' services***. Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of §410.26 are

met.

> **(e)** ***Professional services***. Nurse practitioners can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

42. Under the Act, the term "collaboration" means:

> a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed. (Emphasis Added).

See Section 1861(aa)(6) of the Act.

43. Federal law also defines the conditions that must be met by an NP for services and supplies incident to a physician's professional services; 42 C.F.R. §410.26 provides in relevant part:

> (a) Definitions. For purposes of this section, the following definitions apply:
>
> (1) *Auxiliary personnel* means any individual acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished. (Emphasis Added).
>
> (2) *Direct supervision* means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in §410.232(b)(3)(ii).

> (3) *General supervision* means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service.

E. The Cares Act

44. On March 13, 2020, the President of the United States declared a National Emergency which triggered certain waiver authorities under Section 1135 of The Act. ("The Cares Act").

45. Part of the declaration under Section 1135 of The Act included a temporary waiver for out-of-state providers to be licensed in the state in which they were providing services when they were properly licensed in another state. (See Covid-19 Emergency Declaration Blanket Waiver of Health Care Providers Attached as Exhibit 2; hereinafter identified as the Covid-19 Emergency Declaration).

46. CMS issued in its March 2020 Emergency Declaration for Covid-19, flexibility for Medicare Telehealth services the following guidance:

> **Flexibility for Medicare Telehealth Services**
>
> **Eligible Practitioners**. Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (Cares Act) that broadens the waiver authority under Section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirement of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78(b)(2), which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals who can furnish distant site telehealth services to include all those who are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services. **This waiver will end 151 days after the conclusion of the**

PHE. (Exhibit 2 at p. 1).

47. However, although there was a waiver under the "CARES" Act, for the general licensing requirement for NPs when providing remote telehealth services in a state in which the NP was not licensed, CMS and the United States continued to require that the NP comply with the various state laws for providing those services so as to allow the NP or Life Line to bill the United States for those services only when the various state laws were met. Specifically, in the same Covid-19 Emergency Declaration, CMS cautioned providers as follows:

> **Practitioner Locations**
>
> CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met: 1) must be enrolled as such in the Medicare program; 2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; 3) is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, 4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.
>
> - In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the State. Therefore, in order for the physician or non-physician practitioner to avail him or herself of the 1135 waiver under the conditions described above, the state also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home state. **When the PHE ends, current regulations will continue to allow for a deferral to state law.** (Emphasis Added) (See Exhibit 2 at p. 36)

E. State Law Requirements for NP Practice

48. In Ohio, not only must the NP be licensed in Ohio to provide NP services, but the NP must enter into what is called a collaborative agreement with a physician under Ohio law.

49. Under O.R.C. §4723.01(J), a certified nurse practitioner is defined as an advanced practice registered nurse who holds a current valid license under Ohio law and is designated as a certified nurse practitioner in accordance with Section §4723.42. This section states that in order to receive a license to practice nursing as an advanced practice registered nurse in Ohio, a person must meet the requirements of O.R.C. §4723.41. Ohio Revised Code §4723.41 states in relevant part that in order to be licensed in the State of Ohio, and perform services as a nurse practitioner within the state, the applicant must meet the following requirements:

> 1. Be a registered nurse;
>
> 2. Submit documentation satisfactory to the board that the applicant has earned a master's or doctoral degree with a major in a nursing specialty or in a related field that qualifies the applicant to sit for the certification examination of a national certifying organization approved by the board under section 4723.46 of the Revised Code.
>
> 3. Submit documentation satisfactory to the board of having passed the certification examination of a national certifying organization approved by the board under section 4723.46 of the Revised Code to examine and certify, as applicable, nurse-midwives, registered nurse anesthetists, clinical nurse specialties, or nurse practitioners.
>
> 4. Submit an affidavit with the application that states all of the following:
>
> (a) That the applicant is the person named in the documents submitted under this section and is the lawful possessor thereof;
>
> (b) The applicant's age, residence, the school at which the applicant obtained education in the applicant's nursing specialty, and any other facts that the board requires;

(c) The specialty in which the applicant seeks designation.

50. A nurse practitioner such as Relator has alternative avenues in which to be licensed in Ohio. They are set forth in O.R.C. §4723.41(B)(1) and (2). Those provisions state:

> (1) A certified registered nurse anesthetist, clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who is practicing or has practiced as such in another jurisdiction may apply for a license by endorsement to practice nursing as an advanced practice registered nurse and designation as a certified registered nurse anesthetist, clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner in this state if the nurse meets the requirements set forth in division (A) of this section or division (B)(2) of this section.
>
> (2) If an applicant who is practicing or has practiced in another jurisdiction applies for designation under division (B)(2) of this section, the application shall be submitted to the board in the form prescribed by rules of the board and be accompanied by the application fee required by section 4723.08 of the Revised Code. The application shall include evidence that the applicant meets the requirements of division (B)(2) of this section, holds authority to practice nursing and is in good standing in another jurisdiction granted after meeting requirements approved by the entity of that jurisdiction that regulates nurses, and other information required by rules of the board of nursing.

51. Ohio defines a standard care arrangement as:

> "a written, formal guide for planning and evaluating a patient's health care that is developed by one or more collaborating physicians or podiatrists and a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner and meets the requirements of section 4723.431 of the Revised Code. See O.R.C. §4723.01(N).

52. In addition, under Section 4723.431(A)(1), before a nurse practitioner may engage in providing nursing services in this state, they must first be licensed and then enter into a standard care arrangement with a physician with whom the nurse collaborates. A copy of the standard care arrangement must be retained on file by the nurse's employer – in this case Life Line. Not more than 30 days after first engaging in the practice of nursing as a certified nurse practitioner, the

nurse is required to submit to the Ohio Board of Nursing the name and business address in Ohio of each collaborating physician.[4] Under Ohio Revised Code §4723.431 (B), the standard care arrangement must be in writing and contain all of the following:

> (1) Criteria for referral of a patient by the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner to a collaborating physician or podiatrist or another physician or podiatrist;
>
> (2) A process for the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner to obtain a consultation with a collaborating physician or podiatrist or another physician or podiatrist.
>
> (3) A plan for coverage in instances of emergency or planned absences of either the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner or a collaborating physician or podiatrist that provides the means whereby a physician or podiatrist is available for emergency care;
>
> (4) The process for resolution of disagreements regarding matters of patient management between the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner and a collaborating physician or podiatrist;
>
> (5) Any other criteria required by rule of the board adopted pursuant to section 4723.07 or 4723.50 of the Revised Code.

53. Under O.R.C. §4731.27, unless a standard care arrangement exists with the nurse practitioner and a physician, the nurse practitioner may not practice or provide nursing services in this state. Regardless of whether the federal government waived licensing requirements for out of state NPs, the state law requirement of collaborative agreements as set forth under 42 C.F.R. §410.75 were not waived.

54. Other states have similar statutory and administrative regulations to Ohio which

[4] Ohio Administrative Code §4723-8-04(A) expressly states that prior to engaging in practice a standard care arrangement shall be entered into with each physician with whom the certified nurse practitioner collaborates.

requires out of state NPs to enter into a collaborative agreement with an in-state physician before being permitted to engage in NP care and bill Medicare. In addition, during Covid, the states continued to require an NP enter into a collaborative agreement or meet various administrative requirements in order to provide out-of-state telehealth NP services. These statutory administration regulations were not waived by The Cares Act and were required to be met by Relator and the other nurse practitioners at Life Line who provided AWVs during Covid. These states include:

(a) **Alabama**: Alabama required NPs to enter into a collaborative agreement in accordance with Alabama Code §34-21-81 and Alabama Adm. Code R.610-X-5-.01. The specific requirements a collaborative agreement must include are contained in Alabama Adm. Code R.540-X-8-.08 as well as Alabama Adm. Code R.610-X-5-.09. Under the Fifth Alabama Proclamation signed April 2, 2020 (A)(1)(a) NPs must register their credentials with the Alabama Nursing Board.

(b) **Arizona:** Relator was unauthorized to practice in Arizona. On March 31, 2020, the Arizona State Board of Nursing issued the "Emergency Declaration COVID-19 Response Frequently Asked Questions" requiring NPs to register their credentials.

(c) **Arkansas**: Arkansas required NPs to enter into a collaborative agreement in accordance with Arkansas Code §17-87-102 as well as Arkansas Adm. Rule 067.00.00-004.

(d) **California**: Prior to January 1, 2023, NPs were required to have a collaborative agreement in accordance with California Business and

Professional Code 2835.7.

(e) **Colorado**: Relator was unauthorized to practice. On April 15, 2020, Colorado issued Executive Order 2020-038 requiring NPs to provide services in hospitals or in-patient medical facilities. Relator was unauthorized to provide telehealth care.

(f) **Connecticut**: Prior to January 7, 2022, NPs were required to have a collaborative agreement in accordance with Conn. Gen. Stat. §20-87a(b)(3).

(g) **Delaware**: Prior to August 4, 2021, NPs were required to have a collaborative agreement in accordance with 24 Delaware Code §1936.

(h) **D.C.** – Relator was unauthorized to practice in District of Columbia. On March 13, 2020, District of Columbia issued Administrative Order No. 2020-02 titled "Waiver of Licensing Requirement for Health Care Providers" providing the practitioner must practice at a licensed health care facility located in D.C.

(i) **Florida**: Florida required NPs to enter into a collaborative agreement under Florida Stat. §464.012. Under Florida Stat. §456.47(4), the NP not licensed in Florida must register with the Florida Board of Nursing if she provides services to patients located in Florida using telehealth.

(j) **Georgia**: Georgia required NPs to enter into a "Nurse Protocol Agreement" under O.C.G.A. §43-34-25(a)(10).

(k) **Hawaii:** Relator was unauthorized to provide services to patients in Hawaii. On March 16, 2020, Hawaii signed "Supplementary Proclamation

for Covid 19 Disaster" in which NPs were required to register their credentials with Hawaii's Department of Commerce and Consumer Affairs and the NP was hired by a state or county agency.

(l) **Indiana**: Under Indiana law, NPs were required to enter into a collaborative agreement under 848 Indiana Admin. Code 5-1-1. The guidelines the NP must follow in creation of a collaborative agreement are set forth in Indiana Code §25-23-1-19.4.

(m) **Iowa**: Iowa did not waive their NP licensing requirements so as to authorize NPs to lawfully give care under Iowa Adm. Code 655-3.2.

(n) **Kansas**: Relator was unauthorized to practice in Kansas. Under Executive Order 20-26, signed April 22, 2020, the NP was required to give professional services within a designated health care facility providing medical services necessary to support the response to Covid. Additionally, under Executive Order 20-08 signed March 20, 2020, NPs were not qualified to give telehealth.

(o) **Kentucky**: Relator was unauthorized to practice in Kentucky as on March 31, 2020, Kentucky issued Executive Order 2020-215 requiring out-of-state NPs to register with the Kentucky Board of Nursing and practice at a health care facility licensed by the Kentucky Cabinet for Health and Family Services.

(p) **Louisiana**: Relator was unauthorized to practice in Louisiana because under Emergency Proclamation No. 168JBE2021(S) signed August 31,

2021, the NPs were required to register and confirm their credentials through the NURSYS System.

(q) **Maryland:** Relator was unauthorized to provide services to Maryland patients because under Executive Order Relating to Various Healthcare Matters signed March 26, 2020, Maryland Board of Nursing required any NP with a valid unexpired license to aid in the Covid effort at a licensed healthcare facility as defined under Maryland Section 10-114(d) and if doing so is necessary to allow the healthcare facility to insure continuity of care.

(r) **Massachusetts**: Relator was unauthorized to practice as Massachusetts issued Order Rescinding and Replacing the March 29, 2020 Order of the Commissioner of Public Health Maximizing Healthcare Provider Availability signed April 3, 2020 requiring NPs licensed in another state submit their credentials to the Massachusetts Board of Nursing for verification of good standing. Until January 2021, Massachusetts required NPs to have a collaborative agreement in accordance with 244 Mass. Code of Reg. 4.05(3) and 244 Mass. Code of Reg. 4.22.

(s) **Minnesota**: Relator was unauthorized to Practice in Minnesota. On April 25, 2020, Minnesota issued Executive Order 20-46 titled "Authorizing Out-of-State Healthcare Professionals to Render Aid in Minnesota During the Covid-19 Peace Time Emergency" authorizing out-of-state NPs to render aid. However, NPs must be registered in a healthcare system, hospital,

clinic or healthcare entity in Minnesota. In addition, the healthcare system employing the NP must verify the out-of-state credentials and complete a report submitted to the Minnesota Dept. of Health with the NP's license and length of engagement.

(t) **Mississippi:** Relator was unauthorized to practice in Mississippi because under Mississippi Board of Nursing Proclamation published March 16, 2020, each NP not licensed in Mississippi must complete a Disastrous Emergency Waiver from the Board of Nursing website. Mississippi required NPs to enter into a collaborative agreement in accordance with Miss. Code §73-15-20(3). Miss. Code of Rules 30-2630-1.2 through Miss. Code of Rules 30-2630-1.9 further identifies the specific requirements for an NP and a collaborating physician.

(u) **Missouri:** Relator was unauthorized to practice in Missouri. Missouri required a collaborative agreement pursuant to 20 CSR 2200-4.200. The specifics for the collaborative agreement are set forth in Mo. Rev. Stat. §334.104.

(v) **Montana**: Relator was unauthorized to practice in Montana because under Montana Code Ann. §10-3-118 titled "Interstate Licensure Recognition – Volunteer Professionals." Prior to providing services in Montana, the NP must register with the Montana Board of Nursing to verify her current licensure in the state she is registered in accordance with Montana Regulation 24.101.417.

(w) **Nebraska**: Relator was unauthorized to practice in Nebraska. On March 27, 2020 Nebraska governor signed Executive Order 20-10 titled "Covid-Additional Healthcare Work Force Capacity" in which out-of-state NPs lawfully licensed could provide care pending the completion of a criminal history record check and submission of fingerprints to the FBI. An NP was required to enter into a collaborative agreement under Nebraska Code §38-2308. The parameters of the collaborative agreement is set forth in Nebraska Code §38-2314.01.

(x) **Nevada**: Relator was unauthorized to practice in Nevada because under Executive Order 011 signed April 1, 2020, the NP must have a valid license in good standing in another state, and must notify the Nevada Board of Nursing and provide the requested information to verify her credentials.

(y) **New Hampshire**: Relator was unauthorized to practice in New Hampshire. On March 23, 2020, New Hampshire issued Emergency Order No. 15 titled "Temporary Authorization for Out-of-State Medical Providers to Provide Medically Necessary Services Through Telehealth" requiring the NP to present her credentials to verify they are in good standing at the Nebraska office of the Licensure and Certification.

(z) **New Jersey**: Relator was unauthorized to practice in New Jersey because under New Jersey Assembly No. A3680219 Legislature signed March 16, 2020, for the duration of the public health emergency an NP was limited to the care she could provide directly relating to screening for, diagnosing or

treating Covid 19 unless the NP had a pre-existing provider/patient relationship.

(aa) **North Carolina**: Relator was unauthorized to practice in North Carolina. An NP was required to enter into a collaborative agreement under 21 NC Adm. Code §32M.0101 and 21 NC Adm. Code §36.0810.

(bb) **North Dakota**: Relator was unauthorized to practice in North Dakota because under Executive Order 2020-05.1 signed March 20, 2020, NPs were required to submit their credentials for verification and identification to the State Health Officer and Director of Emergency Services in consultation with the Executive Director of North Dakota Department of Human Services.

(cc) **Oklahoma:** Relator was unauthorized to practice in Oklahoma because under Executive Order 2020-07 signed March 17, 2020, an out-of-state NP was deemed licensed to practice in Oklahoma provided the NP applied her credentials to the Oklahoma Board of Nursing for verification of good standing and to be issued a temporary license to practice. NP was required to enter into a collaborative agreement under Oklahoma Stat. 59-567.3(a).

(dd) **Oregon**: Relator was unauthorized to practice in Oregon because under Oregon Revised Stat. §401.654 an emergency provider or NP may volunteer to perform health care services in Oregon Revised Statute §401.657 at any emergency healthcare center or healthcare facility.

(ee) **Pennsylvania**: Relator was unauthorized to practice in Pennsylvania

because on March 18, 2020, Pennsylvania Dept. of State issued "Pennsylvania Authorized Licensed Healthcare Professionals to Provide Services Via Telemedicine During Covid -19 Emergency" that allowed NPs to provide services to Pennsylvania patients provided the NP was licensed and in good standing in their home state as well as providing the Pennsylvania Board of Nursing, the NPs name, work, mailing address, license type, number and identifying information regarding the government body that issued the license.

(ff) **Rhode Island**: Relator was unauthorized to practice in Rhode Island because under Executive Order 20-21, statutory immunity applied solely to nursing assistants, registered nurses and licensed practical nurses.

(gg) **South Carolina:** Relator was unauthorized to practice om South Carolina. An NP was required to enter into a collaborative agreement under South Carolina Code §40-33-20 and §40-47-20.

(hh) **South Dakota:** Relator was unauthorized to practice in South Dakota. An NP was required to enter into a collaborative agreement under S.D. Codified Laws §36-9A-1(6).

(ii) **Tennessee**: Relator was unauthorized to practice in Tennessee because under Executive Order No. 15, the NP was required to complete the requisite form found under the Department of Health's Professional Board webpage. An NP was required to enter into a collaborative agreement under Tenn. Comp. Regs. 0880-06-.02.

(jj) **Texas**: Relator was unauthorized to practice in Texas because Texas Board of Nursing required out-of-state NPs providing aid for Covid-19 were required to have a delegating physician who was licensed in Texas and practiced prior to the date of the emergency.

(kk) **Utah**: Relator was unauthorized to practice in Utah. Utah required a collaborative agreement until March 14, 2023 under Utah Code §58-31b-803.

(ll) **Vermont**: Relator was unauthorized to practice in Vermont because on March 29, 2021, Vermont governor signed VT S. 117 which permitted out-of-state NPs to provide healthcare services to patients in Vermont as a volunteer at a licensed facility or federally qualified health center and must submit the NP's name, contact information and location the NP is practicing to the office of Professional Regulation.

(mm) **Virginia**: Relator was unauthorized to practice in Virginia because under Executive Order Amended No. 57 signed April 23, 2020, an NP with a license in good standing from another state must provide care at a hospital, physician's office or healthcare facility. Additionally, the facility must submit the NP's name, license type, state of license and ID number.

(nn) **Washington**: Relator was unauthorized to practice in Washington because under Washington Revised Code §43-70-117, the NP must submit confirmation to the Washington Department of Nursing of a licensed in good standing, 10 working days prior to the first day of practice. She must

also register with the Volunteer Health Practitioner Registration System under Washington Revised Code §70.15.040.

(oo) **West Virginia**: Relator was unauthorized to practice in West Virginia because under Executive Order 10-20, signed March 23, 2020, the NP was required to provide her credentials to the West Virginia Board of Registered Nurses for approval before she is able to treat West Virginia patients. She was also required to have a collaborative agreement under West Virginia Code §30-7-15a and §30-7-15b.

(pp) **Wisconsin**: Relator was unauthorized to practice in Wisconsin because under Executive Order No. 16 signed March 27, 2020, the NP was required to obtain a temporary license from the Department of Safety and Professional Services within the first 10 days of working at a temporary or permanent healthcare licensed facility. In addition, the Executive Order only permitted physicians to provide telemedicine to Wisconsin residents.

IV. RELATOR'S EMPLOYMENT

55. With the onset of Covid beginning in March of 2020, Life Line demanded that Relator and the other NP's employed by Life Line begin performing telehealth services for patients located in states in which the NP's were not licensed or had not met the statutory or administrative requirements to provide health services including failing to enter into collaborative agreements with physicians located in those states. For the Relator, these services included performing AWVs with patients located in states outside of Illinois without collaborative agreements or meeting various administration regulations.

56. From April 1, 2020 through August 10, 2021, Relator performed a total of 2,163 AWVs with patients throughout the United States. Of those AWVs, 1926 were with patients in states where Relator had not entered into a collaborative agreement or otherwise failed to meet various state requirements to bill telehealth services to the United States under Medicare.

57. In April of 2020, Relator sought from Jennifer Maze, a senior leader at Life Line, a new contract which would permit Relator to perform telehealth AWVs for Medicare B beneficiaries residing in states other than Illinois. Maze responded that Medicare relaxed the guidelines for NPs to treat patients outside of her state of Illinois.

58. However, Life Line knew in March 2020 that by demanding Relator perform AWV services outside of the State of Illinois without a collaborative agreement, or fulfilling various state administrative requirements, that those services could not be billed under Medicare. For example, after the onset of Covid, on or about the 1st day of February 2021, Life Line required Relator to enter into the Illinois Nurse Practitioner Collaborative Practice Agreement with a physician located in Illinois (hereinafter referred to as the "Agreement"). (Attached as Exhibit 3). Under the Agreement, "[Leonardi] could only practice under this Agreement in the State of Illinois." (Agreement at p. 1). Under Section 3, Prescriptive Authority:

> "[Leonardi] may establish medical diagnoses for patients that are within the NPs scope of practice, and order or prescribe medications and medical devices as authorized by Illinois Law which authorizations may be limited by the terms of this Agreement." (Emphasis Added). (Agreement at p. 2)

59. In Section V of the Agreement – Statement of Approval – Leonardi stated:

> I affirm that I hold current licensure and approval (or provisional authorization) of the Illinois Board of Nursing to practice as an advanced practice nurse in the State of Illinois. I verify that I am competent to provide care to patients of Life Line Community

> Healthcare, Ltd. or its affiliated or associated entities (together "Life Line"), within my scope of practice as described in this Agreement, the attached Protocols and Standard Operating Procedures. (Agreement at p. 4).

60. Similarly, the Illinois physician affirmed:

> I agree that NP is competent to provide care to patients of Life Line as described in the attached protocols and scope of practice. These protocols have been developed and reviewed in accordance with the policies of Life Line. The care rendered by NP will be monitored in accordance with the policies of Life Line and the requirements of the State of Illinois. Variance from the laws, regulations, established policies or procedures or standard of care set by Life Line will be reviewed by the appropriate clinical and management staff at Life Line. (Agreement at p. 4).

61. Oversight under the Agreement was assigned to Jennifer Maze, the Vice President for Life Line. (See Agreement, Exhibit C).

62. After signing the Illinois Agreement, Relator again asked in March of 2021, for an additional contract which allowed her to perform services in states other than Illinois. Molly Mendoza, a Human Resources manager, responded that Life Line doesn't put anything in writing.

63. Consequently, Life Line was aware that during Covid, Relator could only perform services in states in which the statutory and administrative requirements pertaining to an NP's services in a particular state was met. Life Line knew that in addition to Relator, it was required to obtain collaborative agreements for each of its nurse practitioners, or register those NPs in the various states, in order to provide services in those states that required them. Life Line's Chief Legal Counsel Anna Claxton was aware that an individual state's collaborative agreements needed to be signed and was aware that Relator's Collaborative Agreement only permitted her to practice in Illinois. In fact, Claxton forwarded a copy of Relator's signed February 2021 Illinois Agreement with Life Line to Relator on August 13, 2021.

64. By the summer of 2021, Relator's supervisor Kevin Luckow ("Luckow") was demanding that Relator apply for nurse practitioners licenses in Pennsylvania, Kentucky, West Virginia, and Ohio.

65. On August 24, 2021, Relator informed Luckow that she had retained legal counsel for questions that arose during the application process for the nursing licenses in states requested by Life Line. She told Luckow that her attorney had concerns about her engaging in NP telehealth services outside the State of Illinois without having a license in that alternate state. Relator asked for the authority that Life Line used to determine the legality of such action.

66. Luckow angrily responded that Life Line "has people to follow up on this regularly," but "there is always something that [Life Line] was not going to be compliant in." He also stated "there is no system in place to steer participants to specific NPs based on residency."

67. On or about August 27, 2021, Relator again asked Luckow the authority he relied upon in having her perform telehealth in states other than Illinois in which she was not licensed. No response was received.

68. On September 1, 2021, Relator again asked Luckow the authority which supported Life Line's demand that she provide telehealth services to Ohio patients without being licensed in that state. She asked that Luckow agree to speak to her attorney which he refused. His response was that it is not "in his book of work" to prove legality to [her] or talk to attorneys." He demanded that Relator provide the legal authority that Life Line's request was unlawful.

69. On September 9, 2021, Luckow doubled down on Life Line's request and asked that Relator apply for licenses in Michigan and Indiana and to continue to provide AWV care in states she was not licensed, or had a collaborative agreement.

70. On September 17, 2021, Luckow emailed Relator asking if she applied for a license in Ohio.

71. On September 18, 2021, counsel for Relator sent a letter to Life Line's general legal counsel. (A copy of the letter is attached as Exhibit 4). The letter sought from Life Line the authority it relied upon in directing Relator to provide NP services in Ohio by telemedicine when she was not licensed and she didn't have a collaborative agreement with a physician licensed in Ohio. Life Line failed to respond to the letter and/or failed to identify any legal authority which justified its actions in demanding Relator perform telehealth services in states she was not licensed nor had a collaborative agreement.

72. On September 21, 2021, Luckow continued to demand Relator apply to states she was not licensed and to provide telehealth services for Medicare beneficiaries in those states while she was unlicensed nor had a collaborative agreement. The application process placed Relator in a quandary as she was required to certify that she had not previously provided unlicensed NP services in Ohio when, in fact, she had been directed to do so by Life Line. Relator also became aware that she was required to meet the statutory and administrative regulations for all states she was to provide services regardless of Life Line's misguided notion that Covid negated all state's individual requirements in regard to collaborative agreement and/or guidelines regarding telehealth services and registering with the states as a prerequisite to providing AWVs to Medicare beneficiaries.

73. A second letter was sent on September 23, 2021 by Relator's legal counsel, asking Life Line for the legal authority it relied upon in directing Relator to provide nurse practitioner services in Ohio and other states if no collaborative agreement existed between her and a treating

physician in that state. (Attached as Exhibit 5). Life Line was further informed that requiring its nurse practitioners to practice in states where they are not licensed or have a collaborative agreement, were violations of state law and could result in criminal prosecution of Relator.

74. On Thursday afternoon of September 23, 2021, Anna Claxton, Life Line's Chief Legal Counsel, responded by email that she was looking into the issues raised in [Exhibit 5] and "should have a response shortly."

75. The next day on September 24, 2021, Claxton wrote:

> Me (sic) Leonardo (sic) is only being assigned patients where she is licensed. Currently that is Illinois. We are trying to assist her in getting additional licenses (and collaborating agreements as necessary) in other states. Unless and until we get those licenses in place she will be assigned only Illinois patients. I understand she has not been amenable to obtaining additional licenses. We are happy to assist if she changes her mind." (Attached as Exhibit 6).

76. Subsequent to Relator's request for legal authority to permit her to provide NP services without a license or collaborative agreement in Ohio, Life Line began to retaliate against Relator. These acts of retaliation included the systemic redirection of patients that were previously provided to her by her supervisor. For example:

- On September 23, 2021, Relator was told it was not looking good for Illinois patients.
- On October 14, 2021 she was told that no patients in Illinois were scheduled, that was untrue as there were two available and assigned to other NPs.
- On November 17, 2021, she was told there were no patients available for the next day, but that was untrue as there were three available and assigned to other NPs.
- On November 30, 2021, she was told no patients were scheduled, but there were five assigned to other NPs.

77. On October 26, 2021, Life Line attempted to mitigate its unlawful conduct by issuing a company-wide instruction that "All NP's are only going to see patients in their licensed states."

78. Life Line continued its retaliation against Relator for her complaints of unlawful and criminal conduct by moving her status from a full time employee to PRN (work as needed) on January 5, 2022. This occurred even though Life Line claimed in a filing with the State of Ohio that she was terminated on December 17, 2021.

79. On February 8, 2022, Relator engaged in a conversation with Life Line supervisors. During that conversation, Life Line falsely alleged that Relator had refused to sign her newly amended written job description. That reason is untrue as she never refused to sign the job description and, in fact, at the time of her termination she had not received a copy of the new job description she was asked to sign. Life Line subsequently fired her in retaliation for her efforts to stop 1 or more violations of Chapter 3729, and because of her retention of Ohio counsel.

V. LIFE LINE'S ILLEGAL SCHEME

COUNT ONE

A. Life Line's False Claims and Statements and Presentation of Same to the Government.

80. In the Medicare enrollment applications 855(B) and 855(I) that Life Line signed and the Form 1500's that it submitted to Medicare it certified that in submitting claims for payment to the United States, it would abide by the Social Security Act, Medicare regulations, and state laws. It also understood that payment of a claim by Medicare was conditioned upon the claim and the underlying transaction complying with all Medicare laws and regulations including, but

not limited to the FCA.

81. 42 C.F.R. §410.1(a)(2) and 42 C.F.R. §410.1(B) states that Medicare benefits payable under the provisions of Section 410 are a condition of payment.

82. Thus, the Government has made the payment for NP services for AWVs in compliance with 42 C.F.R. §410.75, as a condition of payment.

83. 42 C.F.R. §410.15(a)(ii) refers to Section 1861(aa)(5) of The Act which permits reimbursement to health professionals for AWV services who meet the requirement for each state for which services were provided. A health professional is defined as a nurse practitioner that performs services who is legally authorized to perform those services in the state in which those services are performed and in accordance with the various state laws or state regulatory mechanisms.

84. Section 42 C.F.R. §410.75(c) states that Medicare Part B covers payment of nurse practitioner services only if the services would be covered by a physician and the nurse practitioner performs the services while working in collaboration with a physician.

85. "Collaboration" under §410.75(c)(3)(i) is defined as a process in which a nurse practitioner works with one or more physicians to deliver health care services as provided by the law in the state in which the services are performed. Furthermore, Section 1861(aa)(6) defines collaboration as a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise. Medical direction and appropriate supervision as jointly developed are defined by the law of the state for which the services are performed.

86. From April 1, 2020 through August 10, 2021, Life Line directed Relator to provide

medical services for 2,163 AWVs in 47 states. The date of first and last contact for the AWV 's and the total for each state is listed in Exhibit 7. Relator was not licensed, did not have a collaborative agreement, she did not meet the state requirements for telehealth for any of these states she provided AWV services except for Illinois. Once Relator sought the advice of counsel, and brought the issue of out-of-state telehealth services performed by NPs who are not licensed, who did not have a collaborative agreement, or did not meet state laws allowing them to perform telehealth services, Relator stopped performing out-of-state AWVs by telehealth on August 10, 2021.

87. Other Life Line NPs were also required to perform telehealth AWV services for Medicare Part B beneficiaries in states in which they were not licensed, did not have a collaborative agreement, or did not meet state laws allowing them to perform telehealth services. These names of these other NPs were Arielya Binn, Christine Wiliams, Cynthia Malcolm, Danielle Burgess, Kelsey Browne, Laurie Raher, Melissa McCoy, Raquel Barba, Susan Brock, Tarrah Kaplan, and Wendy Swayne. From April 1, 2020 through October of 2021, each of these NPs performed a similar number of AWVs as Relator in states in which they did not have a collaborative agreement or did not meet state laws allowing them to perform telehealth services.

88. As a representative sample of the thousands of false claims that were submitted by Life Line, Relator provided the following AWV services on the following dates to the patients listed in these tables:[5]

[5] Relator has in her possession documents which identify the last names of these patients, but is not publishing those patients in order to respect their privacy.

Date of Service - May 8, 2020

Patient	State	Service Provided
Kenneth S.	Wisconsin	Billing for AWV Services by out-of-state NP not authorized because Relator did not enter into a collaborative agreement, and only physicians were permitted to provide telehealth services and Relator did not obtain a temporary license from the Dept. of Safety and Professional Services in accordance with Executive Order No. 16.
Leslie B.	South Carolina	Billing for AWV Services by out-of-state NP was not authorized because Relator was a Illinois resident and did not have a collaborative agreement under South Carolina law
Delbert H.	California	Billing for AWV Services by out-of-state NP was not authorized because Relator did not have a collaborative agreement
Wanda H.	California	Billing for AWV Services by out-of-state NP was not authorized because Relator did not have a collaborative agreement
Connie S.	North Carolina	Billing for AWV Services by out-of-state NP was not authorized because Relator did not have a collaborative agreement under 21 NC Adm. Code §32M.0101 and 21 NC Adm. Code §36.0810
Elizabeth M.	South Carolina	Billing for AWV Services by out-of-state NP was not authorized because Relator was a Illinois resident and did not have a collaborative agreement under South Carolina law
Sherry P.	Tennessee	Billing for AWV Services by out-of-state NP was not authorized because Relator did not submit the requisite form to the State of Tennessee under Executive Order No. 15 to allow NP services
Iris C.	Georgia	Billing for AWV Services by out-of-state NP was not authorized because Relator did not register her NP credentials with the State of Georgia to be eligible for a temporary permit and did not possess a collaborative agreement

Date of Service – November 30, 2020

Patient	State	Service Provided
Jane C.	Virginia	Billing for AWV Services by out-of-state NP was not authorized because Relator did not have a collaborative agreement under VA. Code 54.1-2957(D) and under Executive Order Amended 57 and there was no submission to Virginia of Relator's name, license type, state of license and license ID number to allow her to practice
Susan P.	Georgia	Billing for AWV Services by out-of-state NP was not authorized because Relator did not register her NP credentials to be eligible for a temporary permit and did not possess a collaborative agreement
John S.	Ohio	Billing for AWV Services by out-of-state NP was not authorized because Relator did not have a collaborative agreement under 4723.431 and Ohio Administrative Code 4723-8-01
Robert S.	Minnesota	Billing for AWV Services by out-of-state NP was not authorized because Relator did not have a collaborative agreement under Minn. Stat. §148.211 and because when a state of emergency was issued, she did not register her out-of-state nurse practitioner credentials with the State of Minnesota under Executive Order 20-46.
Jean E.	Georgia	Billing for AWV Services by out-of-state NP was not authorized because Relator did not register her NP credentials to be eligible for a temporary permit and did not possess a collaborative agreement
Bonnie E.	Arizona	Billing for AWV Services by out-of-state NP was not authorized because Relator failed to fill out an application to the Arizona Board of Nursing identifying her credentials as a nurse practitioner
Maria D.	South Carolina	Billing for AWV Services by out-of-state NP was not authorized because Relator was a Illinois resident and did not have a collaborative agreement under South Carolina law

89. Relator is aware of the billing practices for Life Line. Once the AWV services were provided by Relator and other Life Line NPs, the Form 1500 bills for these services were submitted to the United States Government for payment by Medicare B within 30 days after the NP AWV service is rendered.

90. Consequently, from April 2020 through October of 2021, Life Line presented claims or caused to be submitted claims contrary its enrollment applications and Form 1500 bills by falsely represented that the services rendered by its staff were made in compliance with the Act, Medicare regulations, the FCA, and state law. The bills were not in compliance as they were submitted by NPs who were not licensed in the states for which they rendered services and had not entered into a collaborative agreement, and failed to satisfy state regulations.

91. As a direct and proximate result of its unlawful conduct, the United States Government paid monies to Life Line for false claims which it otherwise would not have paid if it had known that the claims were false.

B. Defendant's Corporate Scienter

92. At all relevant times, Life Line acted knowingly – that is, with actual knowledge, in deliberate ignorance, or with reckless disregard – with respect to the fact that it was submitting false claims to Medicare as alleged here; and/or that it was making false records or statements material to false claims or to get claims paid.

93. Life Line was familiar with the requirements of Medicare and agreed to abide by Medicare rules and regulations as evidenced by, among other things, its certification in the Medicare enrollment applications identified as Forms 855B, and 855I and the Form 1500 bills. By its certifications, it was also familiar with the various federal and state law requirements that its NPs must enter into collaborative agreements with a resident physician in each state prior to performing AWVs and billing Medicare. It also was aware that its NPs were required to follow the rules and regulations of each state prior to submitting bills to the United States.

94. At all relevant times, Life Line acted knowingly, that is with actual knowledge, in deliberate ignorance, or with reckless disregard with respect to the fact that its actions from at least April 1, 2020 through October 2021, knowingly violated the Act, Medicare rules and regulations, and state law thereby violating the FCA by submitting false bills for payment.

95. Specifically, regardless of the waiver of licensing requirements for NPs in providing out-of-state services under the Cares Act, Life Line knew that it still must fulfill state law requirements for each state while the NPs were providing services to beneficiaries outside the NPs' state of licensure.

96. In April of 2020, Relator sought a contract from Life Line which supported its demands that she provide NP services outside the State of Illinois. She was falsely informed that Medicare had relaxed its administrative requirements so as to allow NPs to provide services outside the state of their licensure.

97. In February of 2021, Life Line required Relator to execute the Illinois Agreement which only allowed her to practice in Illinois yet it demanded she continue to provide telehealth services outside of Illinois without a corresponding collaborative agreement with a physician, or out-of-state license in those states.

98. In March of 2021, Relator again sought a contract to allow her to provide telehealth services outside the State of Illinois and was told by HR manager, Molly Mendoza, that Life Line doesn't put anything in writing.

99. In August of 2021, when Relator sought the legal basis for the out of state telehealth services she was providing to Medicare beneficiaries, she was told by Luckow that Life Line had people to follow up on her request, but there was always something that Life Line was not going

to be compliant in. He admitted there was no system in place at Life Line to steer participants to NPs based on residency.

100. On September 1, 2021, Relator continued to ask for the legal basis for the out-of-state telehealth activities Life Line was demanding she perform. Luckow responded it was not in his "book of work" to prove legality.

101. After receipt of two letters in September 2021 by Life Line from Relator's counsel, requesting the authority to allow Relator to perform AWV services in states where there was no collaborative agreement, Claxton falsely alleged the Life Line was attempting to assist Relator in getting additional collaborative agreements as necessary. That statement was false.

102. Life Line's dismissive conduct towards its compliance concerns, when it had knowledge of potential compliance issues as identified herein, is sufficient to meet the pleading requirement for FCA scienter. The conduct and statements by Life Line's managing agents demonstrates that Life Line knew requiring its NPs to perform AWV telehealth services across state lines without collaborative agreements or fulfillment of state regulatory requirements constituted a violation of Medicare and the FCA.

C. Materiality of FCA Violation by Life Line

103. Under the FCA, a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the government's payment decision. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002, 195 L. Ed. 2d 348 (2016). Under the FCA, in Section 3729, material means having a tendency to influence or be capable of influencing the payment or receipt of money or property.

104. A court's materiality analysis is holistic and considers several factors including: (1) the Government's decision to expressly identify a provision as a condition of payment; (2) whether the Government refuses to pay noncompliant claims, or with actual knowledge of non-compliance, it consistently pays such claims and it does not intend to stop payments; and (3) whether the noncompliance is minor or insubstantial or if it goes to the very essence of the bargain. *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018).

1. Condition of Payment

105. The Government's decision to expressly identify a provision as a condition of payment is relevant to the materiality analysis, but is not automatically dispositive. *Escobar* 136 S. Ct. at 2003.

106. In this case, the government has expressly stated in Section 42 C.F.R. §410 et seq, that payment for AWV services performed by an NP is only authorized if performed under a collaborative agreement with a physician in the state which the beneficiary resides and under the supervision of the physician. Furthermore, the NP must meet state regulations required in order to perform those services within a particular state.

107. The designation of the payment by the government under Medicare for these NP services as a condition for their reimbursement weighs in favor of the issue of materiality.

2. The Government's Prior Response to the Failure of a Medicare Provider to Comply under 42 C.F.R. §410.75.

108. The prior conduct of the government indicates that if a provider fails to comply with state laws relating to 42 C.F.R. §410.75, it is material to its decision to pay Life Line for the false claims it submitted.

109. In *United States ex rel. Norris v. Anderson*, 271 F.Supp.3d 950 (M.D. Tenn 2017), the United States intervened in a case in which it was alleged a provider had submitted false claims by failing to disclose that the nurse practitioners had violated 42 C.F.R. §410.75. Although the case involved the prescription of controlled substances in violation of state law by the nurse practitioners, the government relied upon 42 C.F.R. §410.75 as the basis for the FCA complaint.

110. Similarly, in this case, Relator was relying upon 42 C.F.R. §410.75 as the basis of for the violation of the FCA by Life Line. This materiality analysis weighs in favor of Relator.

3. Life Line's Noncompliance Goes to the Very Essence of the Bargain Between Life Line and the Government.

111. Life Line agreed to only submit claims for payment to the government that were consistent with the Act, Medicare regulations, and state law. In failing to comply with those laws, the government indicates that Life Line is not entitled to payment. Consequently, the allegations in the complaint regarding Life Lines illegal conduct pass the materiality test.

4. Rule 9(b) Allegations

112. Pursuant to Civil Rule 9(b), Relator is required to allege the time, place, content of the alleged misrepresentation, the fraudulent scheme, fraudulent intent and the resulting injury.

113. Relator had pled each of the 9(b) elements with particularity. They are (a) the time of the fraudulent conduct was between April 2020 through October 2021; (b) the place of the alleged fraudulent conduct was at the location of the Medicare Part B beneficiary in states where the out-of-state NP was engaged in AWVs, but did not have a license, a collaborative agreement, or had complied with various state laws where the beneficiary was located; (c) the content of the alleged misrepresentation was the request for payment without Life Line's compliance with various provisions of the Act, Medicare regulations, and state laws; (d) the alleged fraudulent

intent was Life Line's knowing submission of Form 1500's without compliance of Section 410.75 and the various state laws; (e) alleged injury resulting from the fraud are the payments received by Life Line resulting from the presentation of its false claims; and (f) the identify of a representative sample of Medical B beneficiary claims in states where the NPs were not permitted to provide AWV services.

D. The Actions of Life Line are a violation of the FCA.

1. The Actions of Life Line are a Violation of 31 U.S.C. §3729(a)(1)(A).

114. As described herein, from April 2020 through October of 2021 Life Line knowingly or in reckless disregard, or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented, false or fraudulent claims to the United States Government for payment by federally funded health insurance programs based upon its violation of the Medicare laws.

115. Life Line falsely certified it had complied with Medicare laws before presenting a claim for payment from a federally funded health insurance program.

116. The false representations referred to herein were material to the United States' decision to pay the claims presented by Life Line. By presenting claims that were in violation of Medicare laws, Life Line is in violation of the FCA for which the United States seeks reimbursement from Life Line for three times the amount of money paid by the United States, plus civil penalties for each false claim presented to the government.

2. The Actions Of Life Line Are A Violation Of 31 U.S.C. §3729(a)(1)(B).

117. Relator realleges the allegations contained in paragraphs 1 through 116 as if fully rewritten herein.

118. From April of 2020 through October of 2021, Life Line knowingly or in reckless disregard, or in deliberate ignorance of the truth or falsity of the information involved, made, used, or caused to be used, false or fraudulent records or statements material to a false statement to the United States for the purpose of having a false or fraudulent claim paid or approved in violation of 31 U.S.C. § 3729(a)(1)(B).

119. The representations referred to above were material to the United States' decision to pay the claims presented by Life Line.

120. The United States was unaware of the falsity of the claims or statements made, or caused to be made by Life Line, and in reliance of the accuracy of these claims and/or statements, paid for procedures provided to individuals by Life Line insured by federally funded health insurance programs.

121. By presenting claims that were in violation of the FCA, the United States seeks reimbursement from Life Line for three times of the amount of the money paid, plus civil penalties.

COUNT TWO

Retaliation in Violation of 31 U.S.C. §3730(h))

122. Relator realleges the allegations contained in paragraphs 1 through 121 as if fully rewritten herein.

123. In August and September of 2021, the Relator warned Life Line and its management in writing that requests to perform NP services in states in which she was not licensed and did not have a collaborative agreement, was illegal and subjected Relator to criminal prosecution.

124. 31 U.S.C. §3730(h) requires Relator to plead that she engaged in protected activity,

that her employer knew that she was engaged in protected activity, and that she was discharged or otherwise discriminated against as a result of the protected activity. *See, United States of American ex rel. Glenda Overton v. The Christ Hospital, Inc.*, No. 1:13-cv-503, at p. 39 (S.D. Ohio Dec. 31, 2014). (Attached as Exhibit 8).

125. Protected conduct under the statute includes any effort by Relator to stop 1 or more violations of Chapter 3729 whether it involves a specific qui tam action or not. It is to be interpreted broadly. *Id.*

126. Relator has alleged throughout this complaint that she engaged in protected activity, that she and/or her attorney communicated that protected activity, and as a result, she was terminated. Consequently, she has plausibly pled a violation of 3730(h).

127. Subsequently, as described herein, Life Line terminated Relator because of her complaints that Life Line was engaged in one or more acts that were in violation/unlawful under the Medicare laws and the FCA.

128. As a direct and proximate result of Life Line's violation of 31 U.S.C. §3730(h), Relator is entitled to all relief as set forth under 31 U.S.C. §3730(h)(2).

COUNT THREE

Wrongful Discharge in Violation of Ohio Public Policy

129. Relator realleges the allegations contained in paragraphs 1 through 128 as if fully rewritten herein.

130. There exists a clear public policy in the State of Ohio which protects employees from termination when they consult with an attorney regarding matters that would affect their employment and their employer's business. That policy is set forth in the cases of *Chapman v.*

Adia Servs Inc., 116 Ohio App.3d 534, 542-43, 688 N.E.2d 604, 609 (1st Dist. 1997); *Hollingsworth v. Time Warner Cable*, 157 Ohio App.3d 530 (1st Dist. 2004); *Simonelli v. Anderson Concrete Co.*, 99 Ohio App.3d 254, 259, 650 N.E.2d 488 (10th Dist. 1994); *Daniels v. Fraternal Order of Eagle of Tecumseh No. 979*, 162 Ohio App.3d 446, 2005-Ohio-3657, 833 N.E.2d 1253 (2nd Dist. 2005); *Newcomb v. Hostetler Catering, Inc.*, Richland Cty. No. 2006 CA 0040, 2007-Ohio-361 at ¶31 (5th Dist.); *Jacobs v. Highland County Bd.*, Highland Cty. No. 13 CA 20, 2014-Ohio-4194 at ¶22, 20 N.E.2d 300 (4th Dist. 2014); and *Terrill v. Uniscribe Prof'l Servs.* 348 F.Supp.2d 890, fn 6 (N.D. Ohio, 2004).

131. In the summer of 2021, Relator consulted with counsel regarding matters that would affect her employment and Life Line's business including, but not limited to, Life Line's request that Relator perform telehealth services in states in which she was not licensed and had not entered into a collaborative agreement.

132. Relator informed Life Line management of her retention of counsel by email on August 24, 2021. Life Line also received letters from counsel informing it of Relator's retentions of counsel. Copies of those letters are attached as Exhibits 3 and 4.

133. Relator was subsequently terminated in retaliation for her consultation with counsel.

134. Life Line lacked any overriding, legitimate justification for Relator's administrative termination.

135. As a direct and proximate cause of Life Line's retaliatory actions, Relator has been wrongfully discharged in violation of Ohio public policy and is entitled to damages.

136. The actions of Life Line were in wanton and willful disregard of Relator's legal and employment rights which entitles her to punitive damages against Life Line in the amount of One Million ($1,000,000) Dollars.

WHEREFORE, Relator Ellen Leonardi, on behalf of the United States of America, and for herself requests that judgment be entered against Life Line as follows:

1. Life Line be enjoined and ordered to cease and desist from submitting or causing the submission of any further false claims;

2. Judgment be entered in the United States' favor against Life Line in the amount of each and every false or fraudulent claim submitted in violation of the Medicare laws and the FCA and multiplied by three times as provided by 31 U.S.C. §3729(a), and that a civil penalty of not less than $13,946 to 27,894 per claim submitted since 2020 be imposed as provided by 31 U.S.C. §3729(a). Upon information and belief, this amount is in excess of Five Million ($5,000,000) Dollars;

3. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §3730(d), including up to 30 percent of the proceeds of the action or settlement;

4. Relator be awarded compensatory damages, all relief as set forth in 31 U.S.C. §3730(h) and punitive damages.

5. That Relator be awarded against Life Line her costs, including but not limited to, court costs, expert fees, and all attorney's fees incurred by Relator in the prosecution of this suit pursuant to 31 U.S.C. §3730(d)(1); and

6 All relief Relator is entitled for her claim of retaliation in Count Two and Count Three.

7. For such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Mark J. Byrne
MARK J. BYRNE (0029243)
KENNETH F. SEIBEL (0025168)
KATHLEEN R. BYRNE (0099931)
Jacobs, Kleinman, Seibel & McNally LPA
615 Elsinore Place, Suite 290
Cincinnati, OH 45202
Tele (513) 381-6600
Fax (513) 381-4150
E-Mail: mbyrne@jksmlaw.com
kseibel@jksmlaw.com
kbyrne@jksmlaw.com
Attorneys for Relator

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

/s/ Mark J. Byrne
MARK J. BYRNE (0029243)
Attorney for Relator

CERTIFICATION OF SERVICE

I hereby certify that on this 1st day of July, 2024, I electronically filed the foregoing with the Clerk of Courts using the CM/ECF system, which sent Notice of the filing to all registered counsel and parties by operation of the Court's electronic filing system.

/s/ Mark J. Byrne
Mark J. Byrne (0029243)